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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,790	10/24/2001	Daniel A. Keys	2064-181	7203
22471	7590	06/15/2004		
PATENT LEGAL DEPARTMENT/A-42-C BECKMAN COULTER, INC. 4300 N. HARBOR BOULEVARD BOX 3100 FULLERTON, CA 92834-3100			EXAMINER COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/032,790	Applicant(s) KEYS ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 4/23/04 & 12/23/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 10-15 and 18-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-9, 16, 17 and 26-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/23/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the claims**

The Request for Continued Examination filed April 23, 2004 is acknowledged and has been entered.

**NOTE:** In the Reply filed December 23, 2003 on page 13 under the section entitled Amendments to the claims; the Applicant numbered a claim 63 and indicated it as new. However, there was no actual preamble or body to a claim, only a number stating claim 63. Please clarify. (The Reply consisted of pages 1-13 and no claim 63 was found).

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5-9, 16, 17 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (C), part (1) is vague and indefinite because it is unclear how the detection time is varied. Is the initial detection time increased or decreased or does a second detection occur with an increased or decreased amount of time relative to the initial detection time? Please clarify

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5-9, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Herron et al (US 6,287,871).

Herron et al disclose a method for detecting the concentration of an analyte of interest. Herron et al disclose that the method can detect multiple analytes. Herron et al disclose conducting a fluorescent assay to determine the concentration of analyte (col 3, -col 4). Herron et al disclose employing a computer system comprising a CCD camera (col. 7, line 56 – col. 8, line 67) to detect light signals. Herron et al disclose a solution with a known minimum analyte concentration is analyzed and a solution with a known maximum concentration is analyzed and that the process is repeated with progressively larger known analyte concentrations. The photodetection means determines corresponding fluorescence intensities. Herron et al disclose that the computer calculates the concentration of the analyte of interest (col 15 – col 16). Herron et al disclose that the photodetectors (CCD) could be simultaneous or sequential (col 14).

With respect to step (C), (1) and (2), Examiner interprets step (C) and (1) or (2) as recited in claim 1, line 24. Therefore, the instantly recited claims read on the instantly recited step (C) (2).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Lehmann et al (US 5,939,281).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to teach the assay is to determine the concentration of a cytokine.

Lehmann et al disclose specific binding reagents, such as antibodies, for detecting the presence or amount of cytokines in a test sample.

It would have been obvious to one of ordinary skill in the art to use the cytokine specific antibodies taught by Lehmann et al in the method of Herron et al because Herron et al is generic with respect to the analyte that is to be detected and one would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case cytokines.

5. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of Campbell et al (US 4,946,958).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to teach the light signal is a chemiluminescent light signal.

Campbell et al disclose a chemiluminescent label used in analysis, assay or location of proteins, polypeptides and other substances of biological interest (col. 1). Campbell et al disclose that the use of this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques (col. 7).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a chemiluminescent label as taught by Campbell et al into the method of Herron et al because Campbell et al shows that this chemiluminescent label provides a means of improving the sensitivity of measurement of proteins and polypeptides or other substances of biological interest by one to two orders of magnitude by comparison with existing techniques.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al in view of McMillan et al (US 6,057,163).

See above for teachings of Herron et al.

Herron et al differ from the instant invention in failing to specifically teach the well is a multi-well microtiter plate.

McMillan et al disclose the use of a microwell plate to detect luminescence or fluorescence in a sample. McMillan et al disclose that the use of the microwell plate provides a quantitation system for detecting the amount of light emitted by a plurality of samples hold and provides for increased throughput (col 2 & 4).

It would have been obvious to one of ordinary skill in the art to incorporate a microwell plate as taught by McMillan et al into the method of Herron et al because McMillan et al disclose that the use of the microwell plate provides a quantitation system for detecting the amount of light emitted by a plurality of samples held and provides for increased throughput.

### ***Response to Arguments***

7. Applicant's arguments filed December 23, 2003 have been fully considered but they are not persuasive.

Applicant argues that a recited aspect of the present invention relates to the capacity of the invention to determine the presence, absence, activity or concentration of each of multiple target analytes present in a sample. And that as claimed Herron et al fails to teach accomplishing this feat by independently detecting a signal generated by each analyte and then varying the duration of signal detection until the detected signal is within the dynamic range of the detector's assay for that analyte. This is not found persuasive because the instantly recited claims do not require this limitation (see claim 1, part (C)).

Applicant argues that that Herron et al does not teach that the reported presence, absence, activity or concentration of each target analyte is to be determined using the emissions or quenchings of light signals falling within the known dynamic range of the detector's assay for that target analyte. Applicant further states that Herron et al does not address how the requirement that each analyte being assayed be present in the sample at a concentration that would line within the dynamic range of the detector

being used to assay that analyte may be satisfied. This is not found persuasive because Applicant is not on point. The instantly recited claims do not address how this requirement is met and the teachings of Herron et al reads on the instantly recited claims. Applicant directs Examiners attention to Figures 13 and 14 and states that the approach taken by Herron et al., that the CCD camera merely reports the signal elicited by the analytes being assayed and that if the concentration of analyte is below (or above) the dynamic range of the detector, the CCD data will provide an inaccurate report of the true concentration of the analyte. This is not found persuasive because Herron et al still reads on the instantly recited claims and the limitations applicant is relying upon is not required in the instantly recited claims.

Applicant argues that Herron et al fails to disclose or suggest that the dynamic range of an assay can be enhanced through the use of a computer system that has the ability to vary the duration of signal detection independently for each analyte being detected. This is not found persuasive because the instantly recited claims do not require this limitation and as such Herron et al still reads on the instantly recited claims.

Applicants arguments directed to the obviousness rejections concerning Lehman et al, Campbell et al, and McMillan et al are not found persuasive because the rejection concerning Herron et al (the primary reference) is maintained and therefore, it is the Examiner's position that the combination of the primary reference and the secondary references is proper and maintained.

### ***Conclusion***

8. No claims are allowed.



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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Balch et al (US 6,312,960) disclose a method for determining analytes. Balch et al disclose the use of a CCD imaging system and software, which provides automated filtering, thresholding, labeling, and statistical analysis (col 6, lines 28-38). Balch et al disclose the importance of controls (col 1, lines 63-67).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gary Counts  
Examiner  
Art Unit 1641  
June 3, 2004

  
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06/14/04